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Filed: October 5, 1998

REMARKS

Claims 1-12 are pending. Claims 7, 8, 11 and 12 are withdrawn by the Examiner as being drawn to non-elected species. Claim 5 is amended to indicate the ATCC accession numbers for the claimed hybridomas. For the Examiner's convenience, a copy of the currently pending claims is appended hereto. The amendment to the specification serves to provide ATCC deposit numbers as requested by the Examiner.

Response to Rejections Under 35 U.S.C. § 112

Claims 5 and 10 are rejected under 35 U.S.C. § 112, first paragraph as containing subject matter which was not adequately described. The Examiner notes that hybridomas 1D3, 1F3 and 3B7 are required to practice the claimed invention as recited in the claims and as required elements they must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. The Examiner indicates that the claims read on specific antibodies produced by specific deposited hybridomas and that deposit of the hybridomas would satisfy the enablement requirements.

In response Applicants respectfully submit that monoclonal antibodies as described in the claims are fully enabled by the specification and that one of ordinary skill in the art upon reading the specification would be able to practice the invention as claimed. In addition, Applicants are submitting herein a copy of the ATCC deposit receipt indicating that hybridomas 1D3, 1F3 and 3B7 have been deposited in accordance with the Budapest Treaty (Exhibit 1). Furthermore, submitted herein is a Declaration stating that the deposit has been made under the terms of the Budapest Treaty and that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent. (Exhibit 2)

Applicants note that the biological deposit was made on November 4, 1997, while the application from which the present application claims priority was filed on October 6, 1997.

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As suggested by the Examiner, Applicants have submitted herein, a Declaration attesting to the fact that the biological material which is deposited is a biological material specifically identified in the application as filed (Exhibit 2). Applicants respectfully request the Examiner to withdraw this rejection.

Claims 5, 6 and 10 are rejected under 35 U.S.C. 112, second paragraph as being indefinite. Basically, the Examiner indicates that claims 5 and 10 are rejected because the use of 1D3, 1F3 and 3B7 monoclonal antibody as the sole means of identifying the claimed antibody renders that claim indefinite.

In response, Applicants direct the Examiner's attention to amended claims 5 and 10 that include reference to the hybridomas that secrete the claimed antibodies. Applicants respectfully submit that the amended claim specifically identifies the claimed antibody. Applicants respectfully request the Examiner to withdraw the rejection.

The Examiner indicates that claim 6 is indefinite because it is not clear whether the claimed antibody binds to only one set of the recited positions or to more than one set of the recited positions. Applicants respectfully suggest to the Examiner that claim 6 as filed is directed to an antibody that binds one or more of the amino acids positions listed in each enumerated element of the claim. Furthermore, claim 6 contains a Markush group that indicates that the claimed antibody is selected from one of the enumerated elements of the claim. Accordingly, Applicants submit that the claim clearly defines the claimed subject matter and respectfully request the Examiner to withdraw the rejection.

Rejection Under 35 U.S.C. § 102

Claims 1-6 and 9-11 are rejected under 35 U.S.C. § 102(b) as being anticipated by Chuntharapai et al. (FASEB J, 4/30/1996, vol 10(6), PPA 1325 Abstract 1877) as evidenced by Chuntharapai et al. (J. Immunol. vol. 163, pages 766-773, 1999). Basically the Examiner suggests that the Chuntharapai et al. (1996) abstract teaches an antibody labeled 1D3, and that it

is an inherent property of 1D3 that it meets all the limitations of the instant claims as evidenced by Chuntharapai (1999). Applicants respectfully traverse the rejection.

To anticipate a claim in a patent application, a prior art reference must teach every element of the claim (MPEP 2131). In addition, the prior art reference must place the public in possession of the invention. That is, the prior art reference must contain an enabling disclosure (MPEP 2131).

As set forth in MPEP 2121.01, "[i]n determining that quantum of prior art disclosure which is necessary to declare an applicant's invention 'not novel' or 'anticipated' within section 102, the stated test is whether a reference contains an 'enabling disclosure'... ." *In re Hoeksema*, 399 F.2d 269, 158 USPQ 596 (CCPA 1968). Applicants submit that the Chuntharapai et al. abstract (1996) fails to enable the making of the antibodies as set forth in the claims.

Claim 1 is directed to an anti IFNAR2 monoclonal antibody which blocks the binding of first type I interferon but does not block the binding of a second type I interferon to IFNAR2. However, Chuntharapai fails to enable any such antibodies. That is, although Chuntharapai mentions that antibodies were generated and blocking activity of these antibodies was analyzed, Chuntharapai fails to enable one of ordinary skill in the art to make or select an antibody that blocks the binding of IFNAR2 to a first type I interferon but not a second type I interferon.

Initially, Applicants note that Chuntharapai fails to disclose or suggest a mAb that blocks the binding of IFNAR2 to a first type I interferon, but fails to block the binding of a second type I interferon. That is, none of the antibodies as described in Chuntharapai are described as having these properties.

Moreover, the method or conditions for detecting or selecting for antibodies that display both of these properties were not disclosed. Thus, one of ordinary skill in the art, upon reading Chuntharapai would not select a monoclonal antibody that (1) blocks the binding of a first type I interferon, and (2) fails to block the binding of a second type I interferon to IFNAR2. Accordingly, the Chuntharapai (1996) abstract did not enable one of skill in the art to select a monoclonal antibody as described in the present claims.

In addition to failing to provide an enabling disclosure for the selection of antibodies that block the binding of a first type I interferon but not the binding of a second type I interferon to IFNAR2, the Chuntharapai et al. abstract fails to provide a disclosure that would enable one of skill in the art to make such antibodies because the abstract fails to enable the production of the immunogen used to immunize the mice that resulted in the production of the antibodies. That is, although Chuntharapai mentions that soluble IFNARII-IgG immunoadhesion molecules were used to immunize mice, it fails to teach how the immunoadhesion molecules were obtained.

Moreover, Applicants note that not only does the Chuntharapai et al. abstract manifestly fail to enable the practitioner to make the antibody 1D3 referred to therein, but without a sample of the hybridoma cells from the ATCC deposit, the practitioner would have little if any chance of obtaining the 1D3 monoclonal antibody noted above absent a teaching to select an antibody having the aforementioned dual properties. Thus, the Chuntharapai abstract did not place the 1D3 monoclonal antibody at the disposal of the practitioner. Because it is not enabling, the description of the 1D3 antibody in the Chuntharapai abstract does not anticipate the claims.

With respect to Claim 6, Applicants submit that the Chuntharapai et al. abstract fails to teach an anti-IFNAR2 monoclonal antibody selected from the group as set forth in Claim 6, consisting of an antibody that binds to one or more of amino acid positions 49, 51, 52 and 54 in situ in the extracellular domain of IFNAR2, an antibody that binds to one or more of amino acid positions 68, 71 and 72 in situ in the extracellular domain of IFNAR2, an antibody that binds to one or more amino acid positions 133, 134, 145 and 139 in situ in the extracellular domain of IFNAR2, an antibody that binds to one or more of amino acid positions 153, 154 and 156 in situ in the extracellular domain of IFNAR2, an antibody that binds to one or more of amino acid positions 74, 77 and 78 in situ in the extracellular domain of IFNAR2 and an antibody that binds to one or more of amino acid positions 105 and 109 in situ in the extracellular domain of IFNAR2. Applicants note that although the Chuntharapai et al. abstract indicates that "we are further mapping binding sites of these mAbs...by introducing alanine substitutions within hydrophilic portions of the extracellular domain of hIFNARII", there is no teaching or suggestion

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of how this will be accomplished. Upon reading the Chuntharapai, et al. abstract, one of ordinary skill in the art would not know which amino acids of IFNAR2 should be mutated, or in what combination.

In summary, Applicants note that the Chuntharapai et al. abstract fails to teach the skilled artisan how to select for the appropriate antibody and how to detect an antibody that blocks the binding of a first type I interferon but fails to block the binding of a second type I interferon to IFNAR2. Moreover, the Chuntharapai abstract fails to teach the skilled artisan how to prepare the immunizing antigen, or how to determine to which amino acids in IFNARII the antibodies bind. Accordingly, Applicants submit that the Chuntharapai abstract fails to enable the invention as described in the presently pending claims. Applicants respectfully request the Examiner to withdraw the rejection.

Provisional Double-Patenting Rejection

Claims 1-6 and 9-10 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-5 and 9-10 of copending Application No. 08/943,771.

Applicants respectfully request the Examiner to hold this rejection in abeyance until there is an indication of otherwise allowable subject matter.

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CONCLUSION

For the foregoing reasons, Applicants submit that the claims are now in condition for allowance. A notice to that effect is respectfully requested. Should the Examiner be of the opinion that any outstanding matters exist which may be addressed by way of a telephone conference call, she is invited to contact the undersigned to discuss such matters.

Respectfully submitted,

FLEHR HOHBACH TEST

ALBRITTON & HERBERT LLP

By *Daniel C. Hunt, Reg. No. 44,685*

for Richard F. Trecartin
Reg. No. 31,801

Four Embarcadero Center
Suite 3400
San Francisco, CA 94111-4187
Telephone: (415) 781-1989
1030373